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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/593,608  | 09/21/2006  | Yoichi Kato          | 188-105             | 2576             |
| 28349 7590 06/11/2009<br>DILWORTH & BARRESE, LLP<br>1000 WOODBURY ROAD<br>SUITE 405<br>WOODBURY, NY 11797 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| NAFF, DAVID M.  |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 1657  |             |                      |                     |                  |
| MAIL DATE   |             | DELIVERY MODE        |                     |                  |
| 06/11/2009  |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/593,608

**Applicant(s)**

KATO ET AL.

**Examiner**

David M. Naff

**Art Unit**

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/CD/CC)  
Paper No(s)/Mail Date 9/21/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Claims in the application are 1-13.

A response of 3/9/09 to a restriction requirement of 2/6/09 elected Group I claims 1-5 and 7-13 without traverse.

5        Claim 6 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/9/09.

Claims examined on the merits are 1-5 and 7-13.

### ***Claim Rejections - 35 USC § 103***

10        The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

15            (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20        This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

25        Claims 1-5 and 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vyakarnam et al (6,365,149) in view of Tsubouchi et al (6,815,427).

The claims are drawn to a porous body, comprising, as a skeleton constituent, sericin with an average molecular weight of 30000 to 400000, and having a recovery rate of 10% to 100% after 50% compression.

5       Vyakarnam et al disclose porous foam tissue scaffoldings for repair or regeneration of tissue. The foam scaffolding may be seeded with cells, and implanted (col 32, lines 1-4 and 30-32). The foam has pores of 30-200  $\mu\text{m}$  in size (col 5, lines 1-3), and porosities ranging from about 20% to about 98% (col 4, line 32). Various proteins and therapeutic agents can be added to the foams during processing, adsorbed onto the surface, or back filled into the foams after the foams are made (col 17, lines 39-67). Bioactive coatings or surface treatments can be  
10       attached to the surface of the foams. Bioactive peptide sequences can be attached to facilitate protein adsorption and subsequent cell attachment (col 17, lines 62-65).

      Tsubouchi et al disclose using sericin having a molecular weight of about 400,000 isolated from silkworm fibers as a cell growth promoter (col 2, lines 37-43, and col 8, lines 4-24). The sericin can be used as the entire or a part of a cell culture bed material, for biological  
15       applications, as a wound dressing material, a material for vascular endothelium formation (artificial blood vessel), a material for forming an organ, for medical applications, and as a cosmetic material for skin care applications (col 5, lines 25-30 and col 13, lines 31-38). In Example 3 (col 10, lines 23-63), sericin applied to the bottom of a cell culture vessel promoted the growth of fibroblasts cells.

20       When adding proteins to a foam tissue scaffolding during processing, by adsorbing onto the surface, or by back filling into the foams after the foams are made as disclosed by Vyakarnam et al, it would have been obvious to use sericin as the protein as suggested by Tsubouchi et al to obtain the expected result of the sericin promoting the growth of cells which Vyakarnam et al seed into the foam scaffolding before implanting. The foam scaffolding of

Vyakarnam et al inherently has recovery after compression as required by claim 1. The conditions of dependent claims would have been obvious from the conditions disclosed by the references.

***Conclusion***

5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the  
10 organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR  
15 system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/  
Primary Examiner, Art Unit 1657

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DMN  
6/10/09